



PATENT: AH0948Q

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Chung *et al*

Serial No.: 09/431,519

Filed: November 1, 1999

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) Examiner: N. Levy
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) Group Art Unit: 1616
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)
) Atty. Docket No.: AH0948Q

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For: **IMPROVED GROWTH STIMULANT COMPOSITIONS**

Assistant Commissioner for Patents & Trademarks
Washington, D.C. 20231

RESPONSE

Sir:

This Response is in response to the Office Action of March 29, 2001, in the above-identified patent application. Claims 1-20 are pending in the application.

The Examiner rejected Claims 1-13, 16, 17 and 20 under 35 U.S.C. §102 (b) as being anticipated by Deasy 4,874,612. The Deasy formulation is a multi-component implant which contains at least two shaped pieces containing the active compound. See, for example, Deasy, col. 1, lines 50-61. All the pieces contain the active compound *plus* copolymer of lactic acid/glycolic acid. The amounts of the copolymer in the various pieces are different; nevertheless, *both pieces* contain the copolymer of lactic acid/glycolic acid. There are no shaped pieces in the Deasy invention without the copolymer, i.e. with only the active compound. The present invention, on the other hand, uses two formulations, *only one* of which (the controlled release part) contains the polymer. The amended Claim 1 (amended in the Response of January 2, 2001) clearly shows that the first formulation consists essentially of the anabolic agent, while (only) the second one contains both the anabolic agent and the polymer. See, for example, page 7, lines 1-10 and page 7, lines 11-13. The present invention, thus, does not anticipate the Deasy invention. As the present invention clearly articulates, the instant second formulation (which is a controlled-release formulation) releases the anabolic agent much more slowly than the first formulation which, with no polymer being present, releases the agent rapidly. In the case of Deasy, with both pieces containing the polymer, the release rates are not much different, certainly not to the same extent that the instant invention has. Thus, if anything, the present invention should be considered surprising by any standard,



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in view of the Deasy disclosure. Applicants fail to see any anticipation here. Applicants, therefore, respectfully request withdrawal of the 102(b) rejection.

The Examiner rejected Claims 1-20 under 35 U.S. §103(a) as being unpatentable over the Deasy reference and Porter GB 2397484 in view of Horykiewytsch 5,252,561 patent. As stated above, the Deasy reference is different from the instant implant composition. Deasy lacks teaching any part of the formulation that has no lactic acid/glycolic acid polymer. Porter does not teach the use of anabolic agents. Porter simply teaches a method to implant high density particulates such as copper oxide in the form of rod, filament etc., and zinc oxide, to an animal by using cellulose, lactose or starch as a binding agent. There is no dual formulation, no anabolic agent, no controlled release agent and no loading of two different formulations in an implant device and injecting simultaneously into an animal (as the instant application teaches) to produce growth effects; it is simply a nutritional disclosure. The Horykiewytsch reference teaches a method to control the release of an implant into the animal's body by using a weighting agent (e.g. iron powder) (col. 1, lines 8-10 and claim 2), being strictly and only a controlled release formulation- nothing more. Thus, the Porter reference and the Horykiewytsch reference do not add anything to the Deasy reference to make the instant invention obvious.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious over Lee 2,546,759. Lee only teaches a method to introduce a medicament into an animal's body by applying the medication in a specific device or in a vehicle. There is no teaching of dual formulations and no disclosure anywhere where the rate of release of the medicament inside the animal's body is controlled in such a manner as to regulate the growth of the animal. Only the instant application, by its dual formulation approach, teaches such a method. Applicants, therefore, respectfully request withdrawal of this 103(a) rejection too.

The Examiner rejected claims 1-5, 7-13 under 35 U.S.C. 102(b) as being obvious over Ivy, U.S. 4,670,249. The Ivy formulation is a mixture of a growth-promoting hormone *and* a zearalin. Col. 1, lines 19-21 defines growth-promoting hormones as "polypeptide anabolic hormones.....animals." Zearalins are not peptides and are distinguished from growth-promoting hormones throughout the Ivy patent, e.g. col. 1, line 56- col. 2, line 16; col. 3, lines 61-62. The present invention does not contain any growth-promoting hormone, and still, surprisingly offers desirable growth promotion effects. If at all, Ivy should be considered to be teaching away from the present invention. Applicants, therefore, respectfully request withdrawal of this 102(b) rejection too.



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The Examiner rejected Claims 1-20 under 35 U.S.C. 103(a) as being obvious over Deasy, in view of Ivy, O'Callaghan, Sivaramakrishnan and Kim. Contrary to the Examiner's statement, Deasy does NOT provide the instant implants. On the other hand, and as explained above, all the pieces of Deasy contain the lactic acid/glycolic acid polymer. The instant invention's immediate release formulation does not contain that. None of the additional references that the Examiner has included above teaches that aspect or the totality of the present invention. Even though the Examiner has combined five references, they still do not teach the present invention. Applicants, therefore, respectfully request withdrawal of this 103(a) rejection too.

In summary, the instant invention discloses a dual formulation, only one of which contains a polymer in addition to the anabolic agent. None of the references cited by the Examiner, be alone or in combination, teaches that essential nature of the present invention. Applicants, therefore, believe that whether used alone or in combination, the references cited by the Examiner do not anticipate or make the invention obvious. There being no other rejection pending, Applicants believe that Claims 1-20 (as amended in the Response Applicants filed on January 2, 2001) are in allowable condition. Such an action is earnestly requested. If the Examiner has questions, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Dr. Palaiyur S. Kalyanaraman
Registration No. 34,634

July 6, 2001
Schering-Plough Corporation
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530
Tel: 908-298-5068
Fax: 908-298-5388

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT, K-6-1-1990 PALAIYUR S. KALYANARAMAN REG. No. 34634
Signature	
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